

**ASEPT® Drainage System
Information for Patients,
Carers & Healthcare
Professionals**

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The ASEPT® System

Repeated pleural effusions or ascites can be treated in an outpatient setting using the ASEPT® System. A tunnelled permanent drainage catheter is implanted in the pleural cavity (pleural effusion) or in the peritoneal cavity (ascites) by means of Seldinger technique. After completion of this surgical procedure, the patient can return home with the ASEPT® System in situ.

The drainage is carried out every 1 – 2 days in accordance with instructions provided by the Physician. Therefore, preventing further punctures into the pleural or peritoneal cavity as they are no longer necessary.

General Benefits for the Patient

Improved Quality of Life

The direct symptoms, e.g. dyspnoea, are improved with the drainage. Spontaneous pleurodesis occurs within one month in 59% of the cases. Drainage using the ASEPT® system is virtually painless, when compared with other forms of treatment, e.g. chemical pleurodesis.

Outpatient Drainage

Due to utilising the outpatient setting by connecting the ASEPT® drainage bottle onto the catheter at home, patients now no longer have time consuming and exhausting visits to the hospital. The drainage can now be carried out by either the patient themselves, a family member, or a District Nurse.

Minimally Invasive

The catheter is inserted in the pleural or peritoneal cavity by means of the Seldinger technique - this minimises the risk of internal organs being injured. The procedure which is carried out under local anaesthetic can take place either as an inpatient or as an outpatient.

Prevention of Revolving Door Effects

Being constantly connected to a drainage bag may lead to a dislocation of the catheter inside the patient. If this occurs the result would be a new catheter system and an overnight inpatient stay at the hospital. Through a steady drainage by means of vacuum, the patient has the greatest possible mobility and therefore quality of life. It is recommended to regularly drain with suction to prevent possible (protein) accumulations within the catheter and valve.

Safe

The treatment has a low infection rate. Due to the tunnelled application of the catheter, it provides an effective barrier against infection. In addition, the drainage bottles are under negative pressure and prevents contaminated fluids from penetrating the effusion space.

Different Strengths of Suction

Whilst the patient is being treated as an outpatient, there are two alternative drainage bottle systems available. Depending on the symptoms, as well as individual preferences, the therapy can be done either by means of high vacuum (**ASEPT® Drainage Kit**) or low vacuum and gravity drainage respectively (**ASEPT® Drainage Kit L**).

Safety Valve

The ASEPT® valve closes automatically, is easy to clean, and connects the catheter with the drainage bottle in an extremely hygienic way. No end caps or fixations are required. Even after numerous connections the valve remains in perfect working order.

Minimised Dislocation Risk

A polyester cuff is positioned in the tunnel and situated under the skin. This cuff allows the patient's tissue to grow, minimising the risk of dislocation or infection.

Detailed View

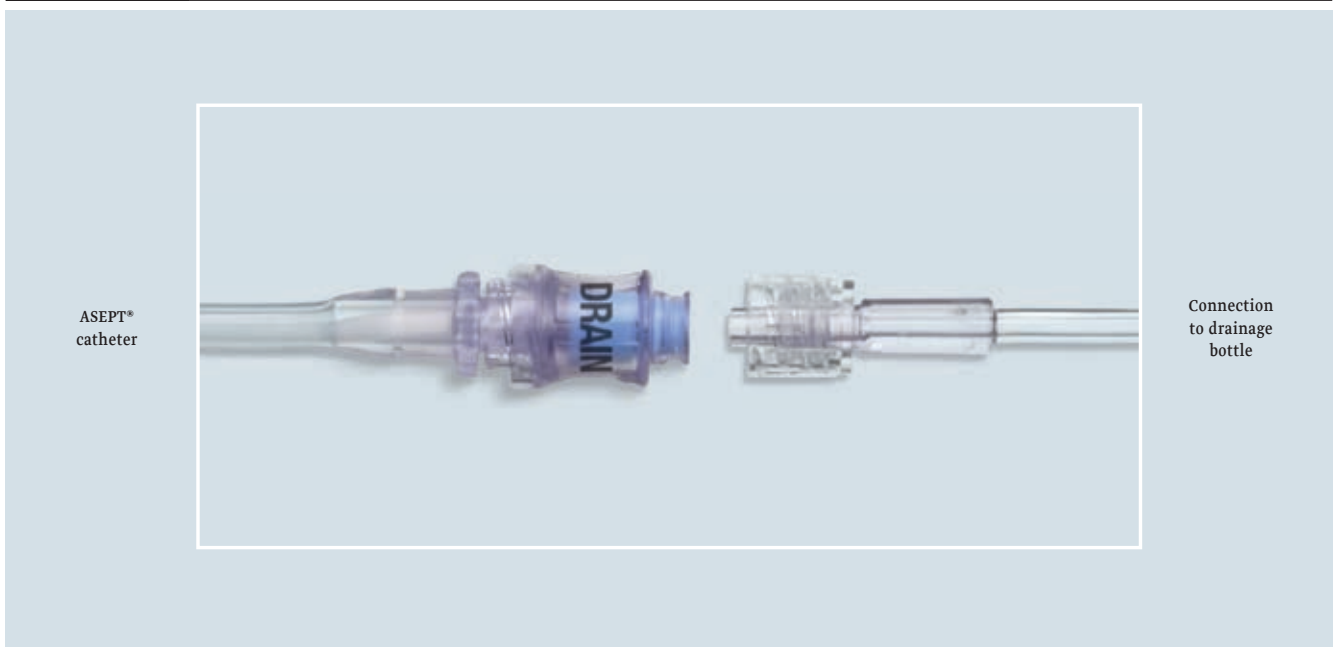


Figure 1: ASEPT® safety valve: self-closing, no cap or fixation required

Information for Patients

Your Doctor is planning the insertion of a permanent drainage catheter or has already inserted one. This catheter allows your effusion - either in the chest (pleural effusion) or in the abdomen (ascites) - to be drained without repeated punctures.

The following pages will explain the procedure of the therapy and will answer the most important questions already in advance - please don't hesitate to get in contact via the telephone number at the back of this booklet if you need any advice or guidance.

Draining the Effusion Fluid

The implantation of the catheter can be carried out as an inpatient or outpatient. It only takes a few minutes and is performed under local anaesthetic. After an appropriate observation period you can then return home.

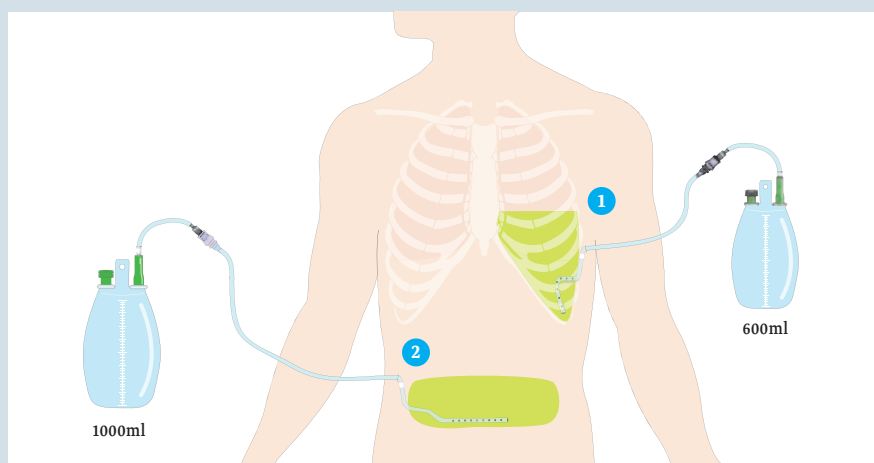


Figure 2: Potential entry sites of the permanent drainage catheter depending on type of effusion (1. Pleural Effusion, 2. Ascites)

The actual drainage treatment is carried out at home. Circumstantial punctures in the hospital or the Doctor's practice are no longer necessary. This is made possible by vacuum bottles that are connected to the catheter via a rotary joint in order to collect the effusion fluid. Symptoms such as shortness of breath or a feeling of pressure become weaker. After the drainage, which lasts only a few minutes, the bottle can be removed and disposed of.

The drainage of your effusion is normally carried out by a District Nurse, however it may be possible to teach you or a family member how to perform the drainage. Education and training will be provided on how to carry out the drainage, and ongoing support will be available.

Your Doctor will specify how often the effusion should be drained. Usually, it is every 1 to 2 days. Please keep a diary of the drained amount as it can decrease or even completely run dry. In this case the catheter can be removed entirely. Simply fill in the diary at the end of this booklet where you can also enter the type and size of drainage bottle used, and a description of the colour and consistency of the fluid drained.

The ASEPT® Drainage System in Detail

The ASEPT® drainage system consists of a permanent implanted drainage catheter with self-valve and vacuum cylinders. These are connected via an easy-to-use rotating connection to the catheter.

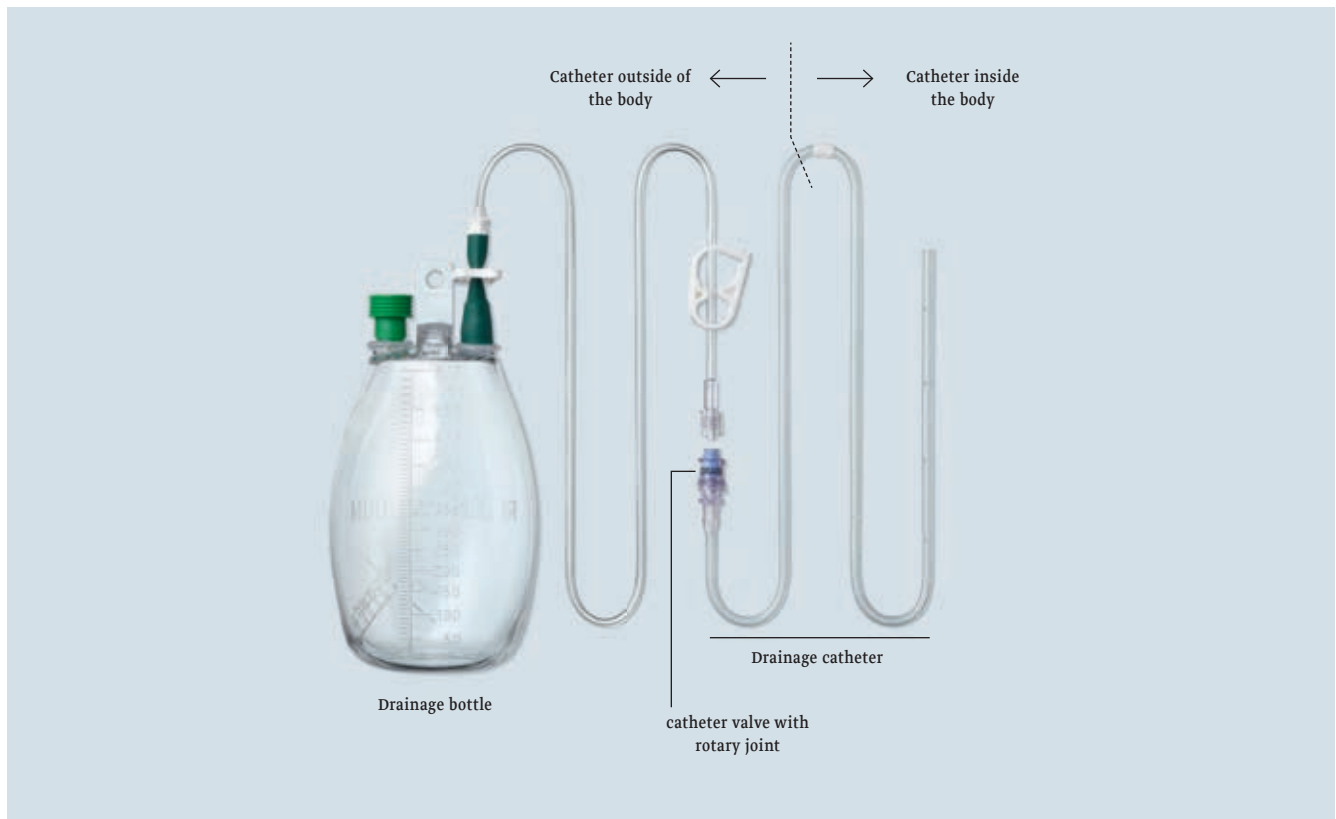


Figure 3: Overview of the ASEPT® Drainage System

There are two types of drainage bottles: The ASEPT® 600ml Drainage Kit can be used for pleural effusions, for ascites the ASEPT® 1000ml Drainage Kit can be used. Your doctor will define the appropriate size for you and whether your fluid should be drained using either high vacuum or low vacuum. Each drainage bottle is delivered as a set. It contains all sterile consumables necessary for hygienic drainage: gloves, disinfectant wipes, and dressing material.

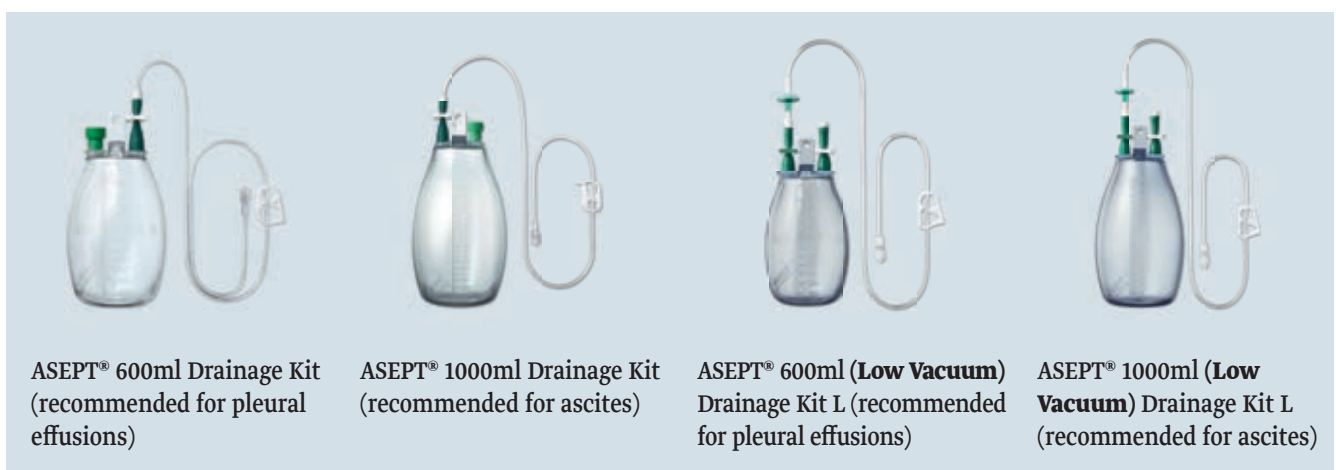


Figure 4: The different types of the ASEPT® Drainage Kits

The ASEPT® Drainage Kit

Safely Pre-Evacuated

The bottles have been pre-evacuated and are under negative pressure. The effusion fluid is simply suctioned by it being connected to the ASEPT® catheter. A vacuum indicator displays the functionality of the bottle. No additional devices are required for the drainage.

Complete

The ASEPT® Drainage Kits and ASEPT® Drainage Kits L include sterile consumables which can be used to sterilise the valve and cover the ASEPT® catheter.



The ASEPT® Drainage System Kit contains the following sterile consumables:

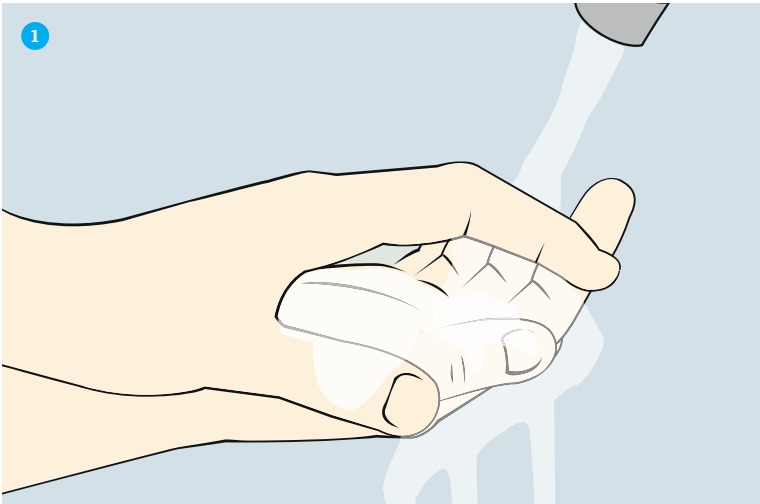
- ① Self-adhesive surgical dressing
- ② 3 alcohol swabs
- ③ Foam catheter pad
- ④ Gauze compresses
- ⑤ Emergency clamp
- ⑥ 2 pairs of gloves



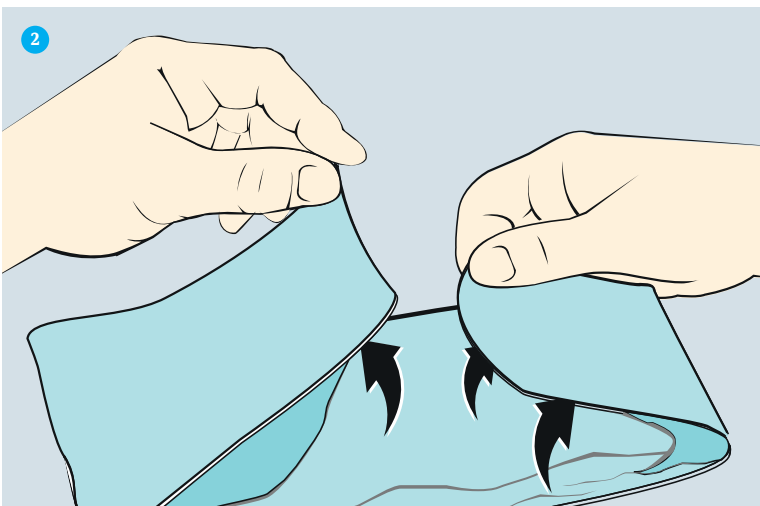
Vacuum indicator (not available with ASEPT® Drainage Kit L due to existing ventilation filter):

- ① Contracted: Vacuum intact
- ② Extended: Vacuum not intact

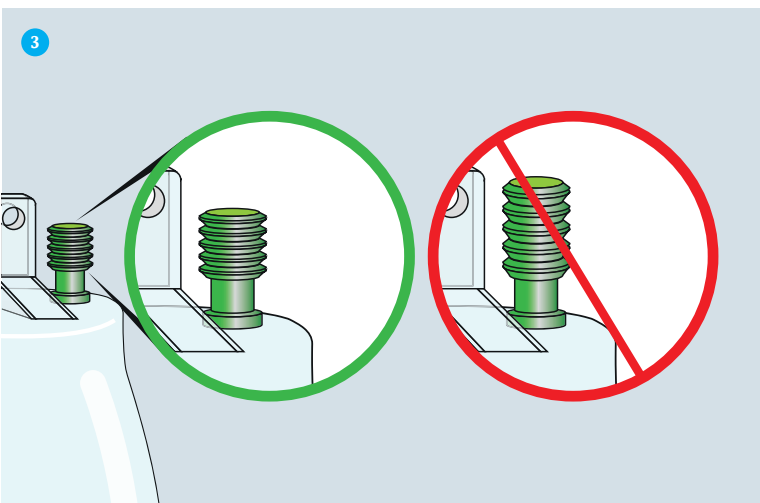
The ASEPT® Drainage Kit – Application & Step-by-Step Guide



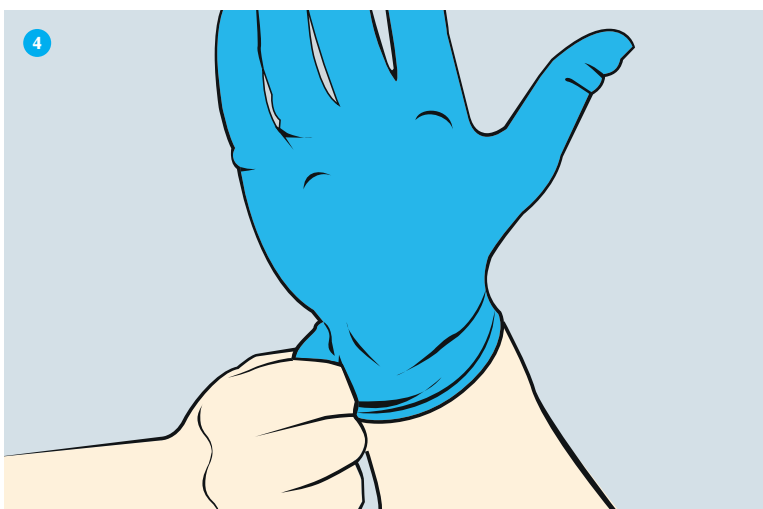
(1) Before beginning the drainage, wash your hands with soap and water for 1 minute.



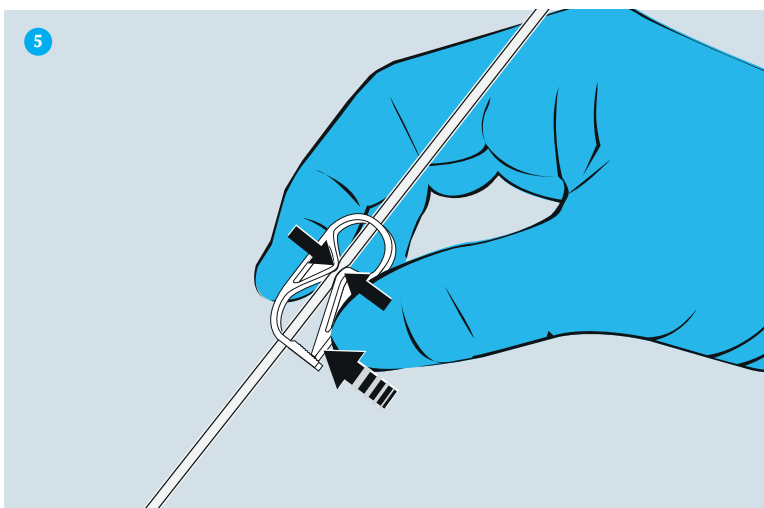
(2) Collect your equipment and place on a cleaned tray or a cleaned flat surface using an antibacterial wipe. Open procedure pack bag, remove the tape and unfold blue wrapping.



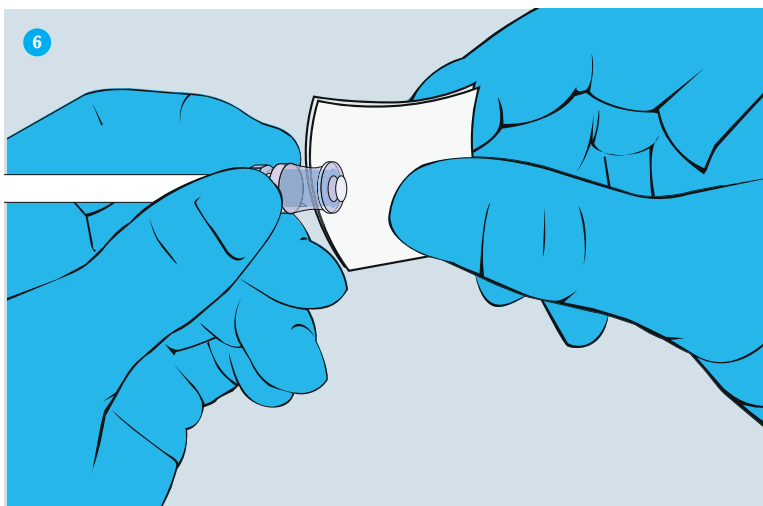
(3) Vacuum indicator on top of ASEPT® vacuum bottle must be retracted. If not, discard the bottle.



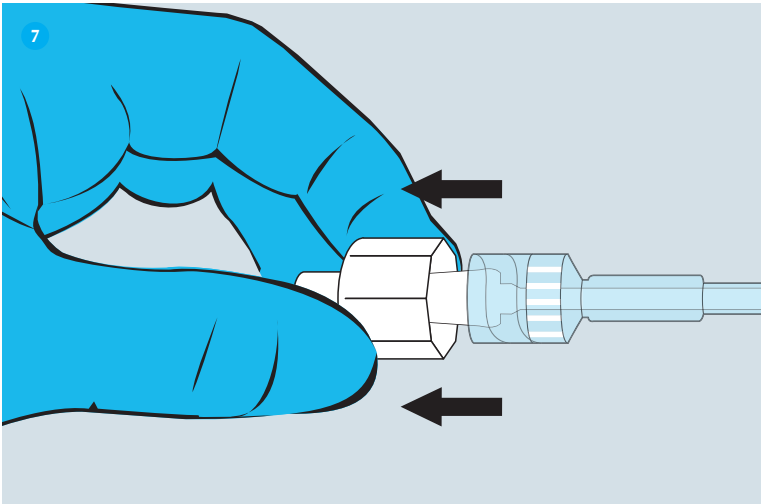
(4) Decontaminate your hands with a hand sanitiser gel and put on the sterile gloves by picking them up by the wrist. Both gloves fit either hand.



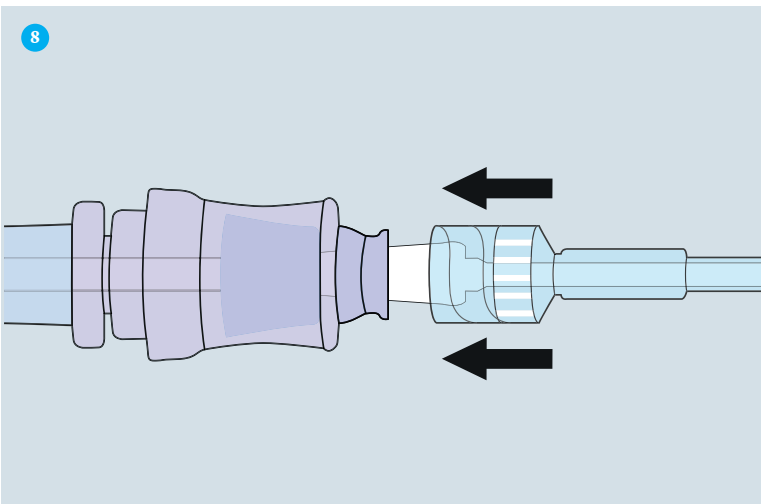
(5) Squeeze the pinch clamp on the drainage line to the extent that the tube is completely closed.



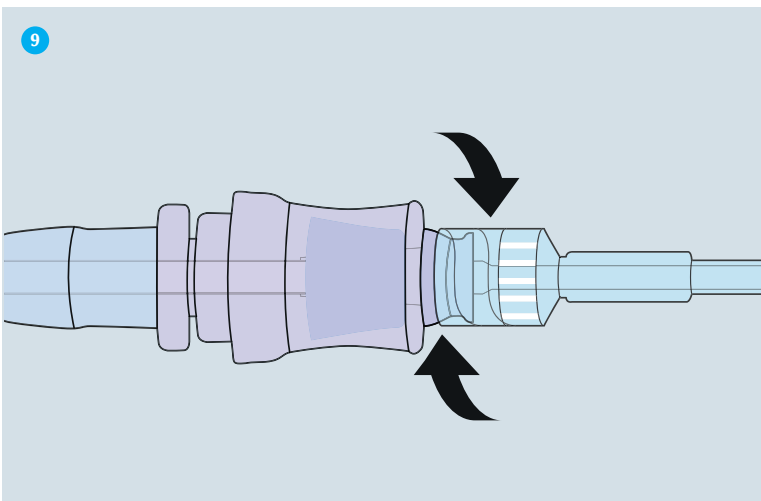
(6) Remove the current dressing and both the gauze and foam pads that are covering the inserted catheter, then clean valve surface and around valve with an alcohol swab.



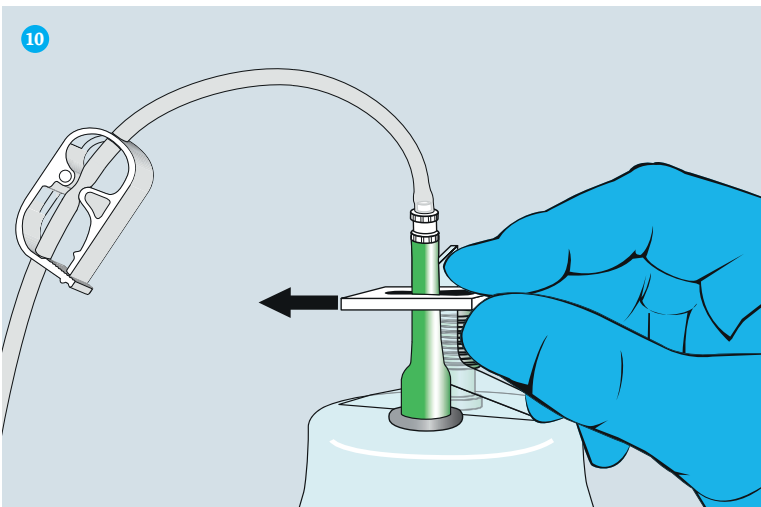
(7) Remove the protection cap located at the end of the bottle's drainage line.



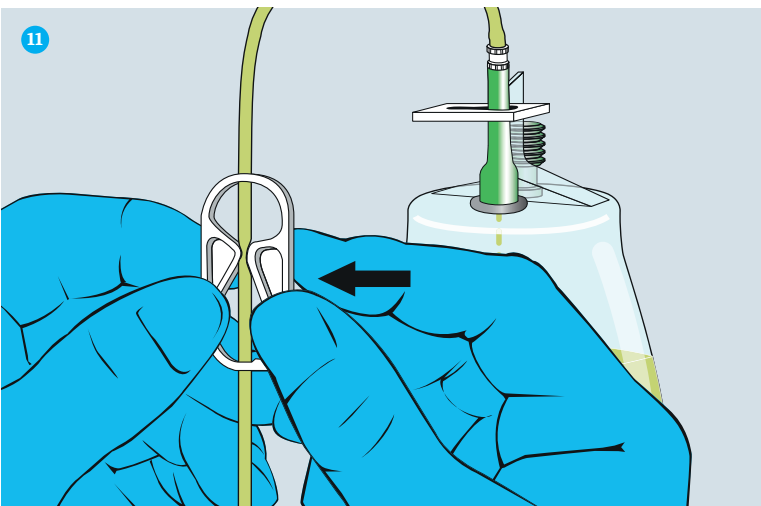
(8) Push the bottle's ASEPT® connector into the catheter's silicone valve surface.



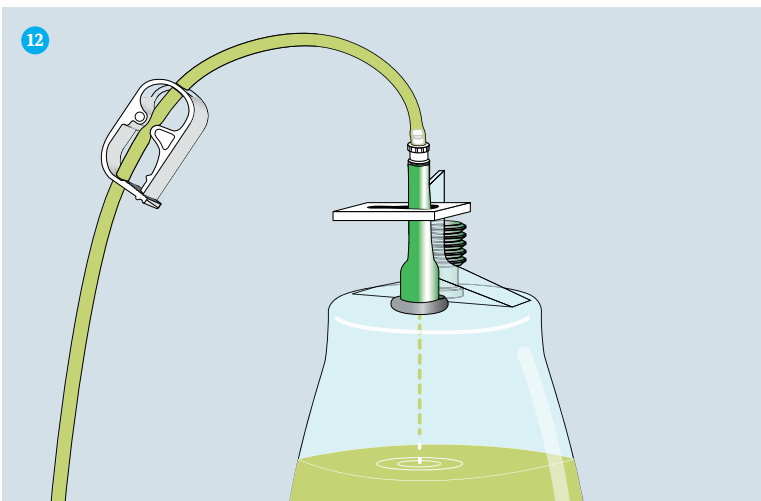
(9) Screw the ASEPT® connector clockwise into the valve.



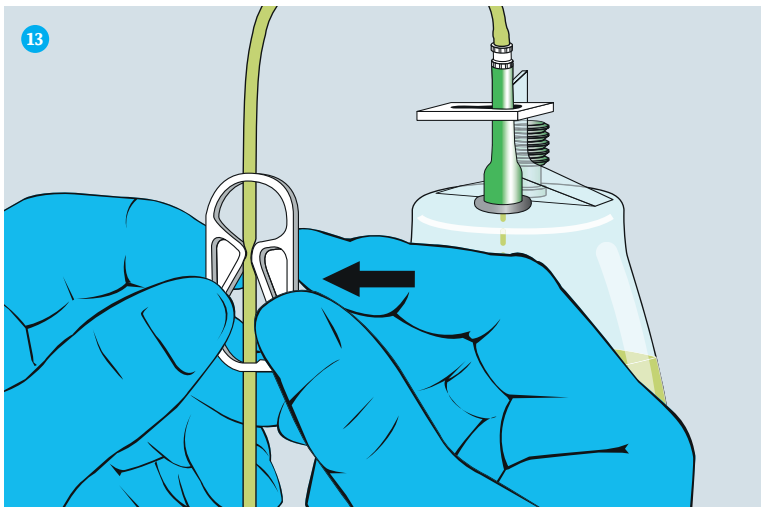
(10) Push the slide clamp until it no longer pinches the green tube closed.



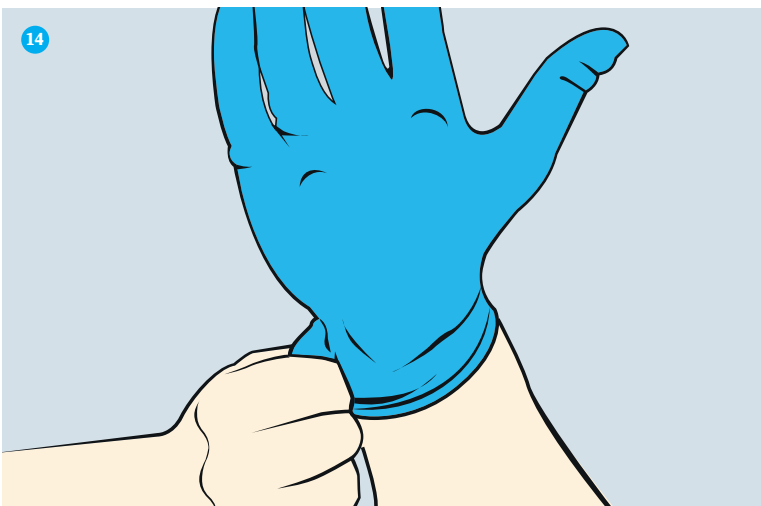
(11) Now slowly 'unpinch' the clamp on the drainage line to begin draining the effusion fluid.



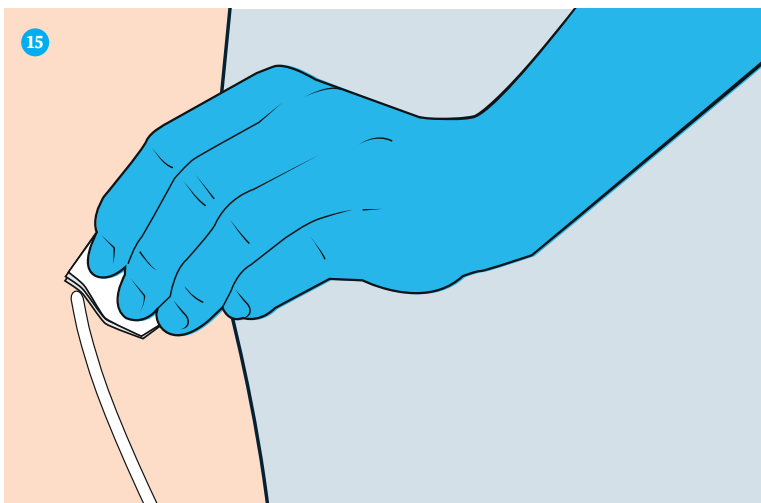
(12) Liquid flows into the bottle. Eventually squeeze the clamp until partially closed to adjust the flow.



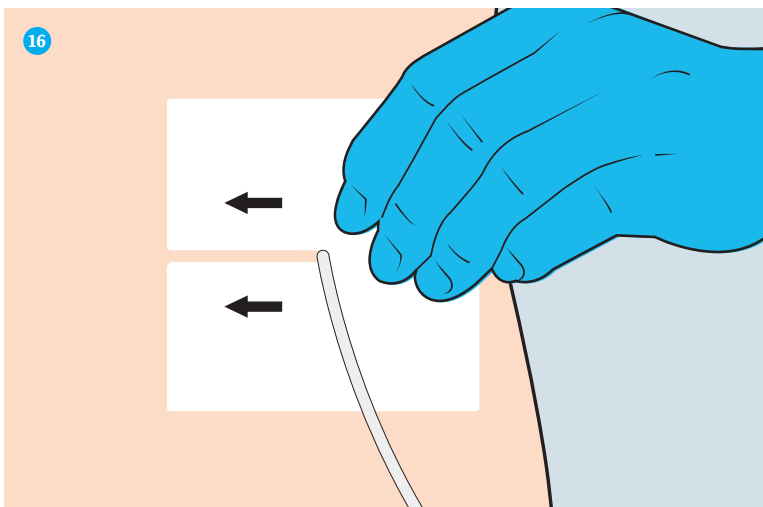
(13) After draining the effusion fluid, slowly close the pinch clamp and loosen the valve connection.



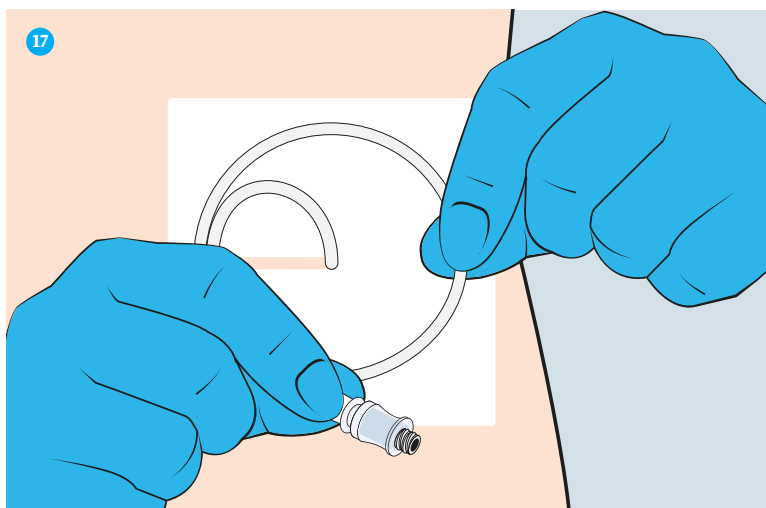
(14) Put on the 2nd pair of gloves provided by picking them by the wrist. Both gloves fit either hand.



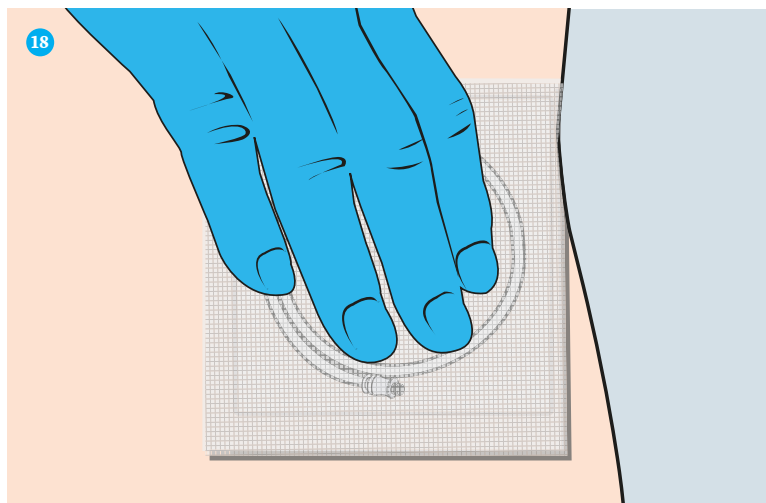
(15) Disinfect the catheter exit site and the valve, each with one alcohol pad.



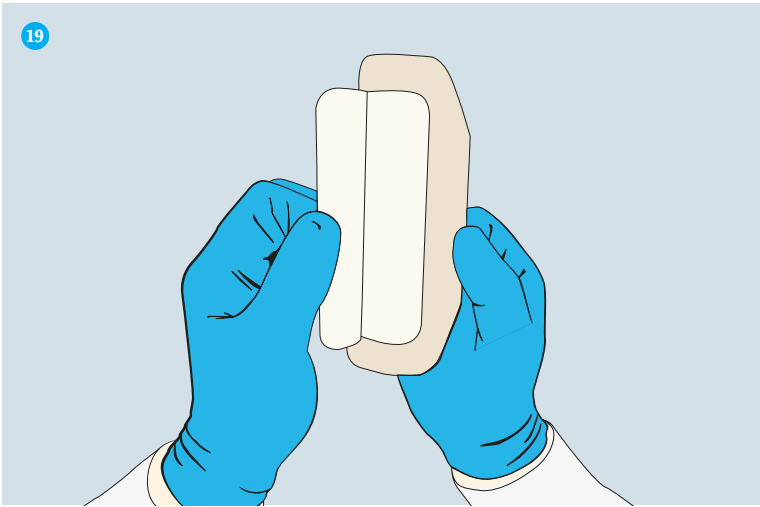
(16) Place the new foam catheter pad around the catheter.



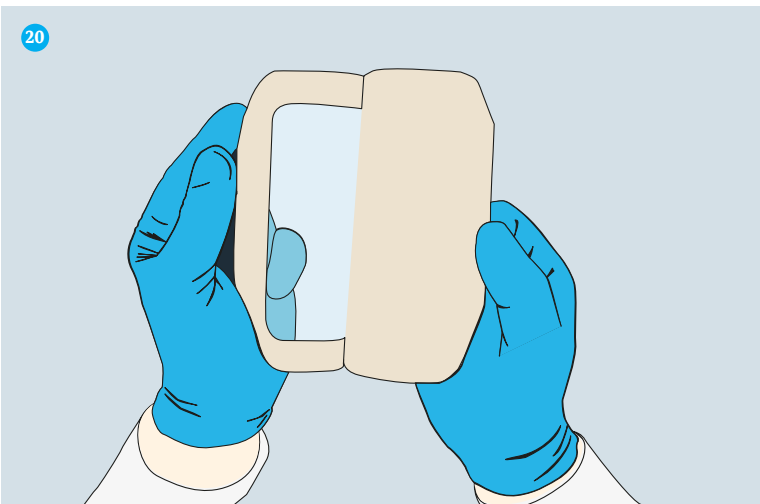
(17) Curl catheter around in a circle and place it on the foam pad.



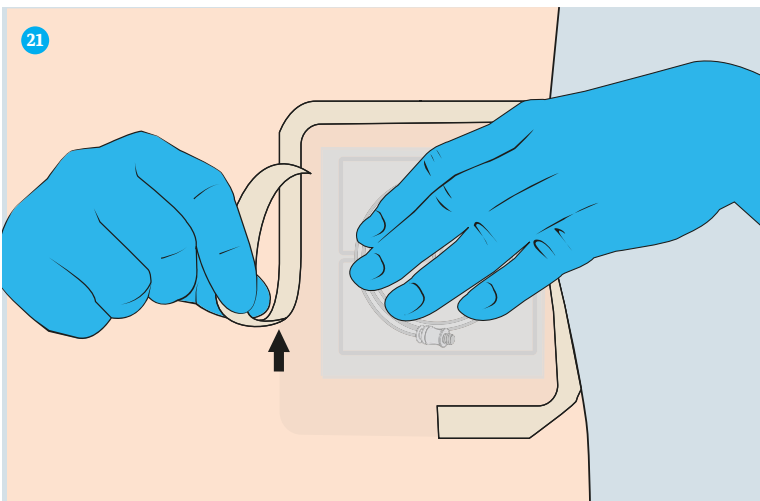
(18) Cover the catheter with the new gauze pads.



(19) Remove and peel away the middle rectangular section of the two pieces of paper from dressing. The paper frame will remain on that side of the dressing.



(20) Peel the printed paper off the patch. The adhesive side of the patch is now exposed.



(21) Centre dressing over the gauze pads and press it down. Remove the paper frame.

Outpatient Drainage Video Demonstration (internet access required)

Using the camera on your mobile phone or tablet, please scan the below QR Code to watch the ASEPT® Drainage System - Outpatient Drainage video for further support.



<https://www.youtube.com/watch?v=m4Mv7ERayTI>



Patient ID Card & Contact Information

Name	
Address	
Telephone Number	
Date of ASEPT® Catheter Implantation	
Hospital	
District Nurse Name & Location	
District Nurse Contact Details	

Type of Catheter

☐ Pleural ☐ Peritoneal

Type of Drainage Bottle Required

☐ ASEPT® 600ml Drainage Kit ☐ ASEPT® 1000ml Drainage Kit
☐ ASEPT® 600ml Drainage Kit L ☐ ASEPT® 1000ml Drainage Kit L

Drainage Diary

[illegible]

Date & Time	Drained Volume (ml)	Notes / Duration of Drainage / Colour of Fluid / Type & Size of Drainage Bottle Used

[illegible]

Date & Time	Drained Volume (ml)	Notes / Duration of Drainage / Colour of Fluid / Type & Size of Drainage Bottle Used

Frequently Asked Questions

About which distinctiveness should I inform my Doctor?

- ▶ Changes of the effusion fluid, e.g. colour
- ▶ Redness of the catheter exit site
- ▶ Fluid leaking from the wrong site, e.g. through hole in the catheter
- ▶ Decrease or increase of the drained amount of fluid volume
- ▶ Sudden stop of the drainage
- ▶ Accidental extraction of the catheter

When will the catheter be removed?

If the drained fluid volume is less than 50ml on three consecutive drainages, your Doctor can decide to remove the drainage catheter.

Am I allowed to take a shower?

Yes. The self-adhesive dressing in the drainage kit is waterproof and breathable. Your Doctor will tell you when exactly you can start having a shower after the implantation. Please make sure that the dressing completely covers the gauze compresses.

How often should effusion fluid be drained?

Your Doctor will inform you how often you should drain. After medical consultation patients often can decide on their own, depending on the severity of the symptoms.

Who can I contact if I have questions concerning the handling?

Address your questions regarding drainage and/or handling to your Doctor or District Nurse. If you have any questions about the ASEPT® products you may contact us directly.

Can ASEPT® products be used several times?

No. The ASEPT® system is made only for single use. Also, they should not be used when unsterile. Resterilisation is not possible.

Is there a maximum drainage volume?

Yes. The maximum drainage volume for pleural effusions is 1000ml. For ascites, there is a maximum of 2000ml. If these quantities are exceeded, there is a risk of increased reproduction of the effusion. Please inform your doctor if you still suffer from pain after draining at these maximum volumes.

Is the drainage painful?

It is normal that you may feel a slight discomfort or need to cough when draining the fluid. If this is the case, please close the pinch clamp on the drainage line to interrupt the flow for a few minutes. If you do not feel better stop the drainage and contact your Doctor or District Nurse.

Does the catheter valve require a cap?

No. The valve and the catheter are simply bandaged up with compresses and plasters. Separate caps are not necessary due to the luer-lock valve connection. A proper disinfection of the valve before and after drainage with the enclosed alcohol swabs is crucial.

What function does the blue clamp have?

If the catheter has been pierced or cut, please act as follows:

- ▶ Compress the catheter firmly with your fingers.
- ▶ Pull the blue emergency slide clamp - which comes with the bottle - over the catheter between the patient's body and the exit site to close the catheter.
- ▶ Immediately inform your Doctor or District Nurse.

Recommendation: Put a blue clamp ready to hand aside. It does not have to be sterile.

How long do the threads have to remain lying?

Your Doctor determines when the threads can be drawn. Usually it takes 7 - 10 days until the threads can be removed - the holding thread needs 30 days until removal.

What is the ordering information District Nurses will need for additional ASEPT® products?**Ordering information****ASEPT® 600ml Drainage Kit**

Reference Code	Unit of Issue
P09080003	10

ASEPT® 1000ml Drainage Kit

Reference Code	Unit of Issue
P09080004	10

ASEPT® Replacement Valve

Reference Code	Unit of Issue
P09080005	5

ASEPT® Drainage Line Set

Reference Code	Unit of Issue
P09080006	10

ASEPT® 600ml Drainage Kit L

(Low Vacuum)

Reference Code	Unit of Issue
P09080007	10

ASEPT® 1000ml Drainage Kit L





(Low Vacuum)

Reference Code	Unit of Issue
P09080008	10

Please Affix Hospital Sticker Below

Contact

Should you have any questions our Customer Solutions Team is happy to advise you.

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